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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/372,036 08/11/99 SCHUBERT

P MERCK1694D2

023599 HM12/0824  
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EXAMINER

BASKAR, P

ART UNIT

PAPER NUMBER

1645

DATE MAILED:

08/24/01

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

## Office Action Summary

Application No.  
09/372,036

Applicant(s)  
SCHUBERT PETER ET AL

Examiner  
Padma Baskar

Art Unit  
1645



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on Jun 11, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 39-62 is/are pending in the application.
- 4a) Of the above, claim(s) 39-41 and 44-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 42, 43, and 50-62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 39-62 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other:

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### **Response to Amendment**

1. The amendment filed on 6/11/01 has been entered into the record. Claim 42 has been amended. New claims 59-62 have been added to the elected invention since the claims recite antibodies. Claims 42, 43, 50-62 are under examination.
2. In view of applicant's amendment to the specification, the Examiner has withdrawn the objection to the priority.
3. In view of applicant's clarification of record and the Oath and Declaration filed with the parent application 08/075,248, Examiner has withdrawn the objection to the Declaration.

### **Rejections Withdrawn**

4. In view of applicants arguments of record and the Examiner has withdrawn 35U.S.C.112 first paragraph rejections and second paragraph rejections. The Declarations submitted by Drs Schubert and Vormbrock are not necessary regarding the issues raised by the Examiner.

### **New Rejections**

5. Claims 42,43, 50-59 and 61 are rejected under 35U.S.C.(102 b) as being anticipated by Kohler et al 1990 (Infection and Immunity, 58, 1943-1950)

Claims are directed to an isolated antibody which specifically binds to the p60 protein from pathogenic listeria, wherein said antibody binds an epitope from the peptide, SEQ.ID.NO: 17, 20, 26, 29, 30 or 31 and said antibody obtained by immunizing said peptides.

Kohler et al 1990 disclose anti-p60 antiserum raised against purified p60 (i.e., inherently contains epitopes of SEQ.ID.NO: 17, 20, 26, 29, 30 or 31) listeria protein in rabbits. This is a polyclonal antibody which binds to p60 of Listeria (Fig 1) wild type and recombinant p60. In the absence of evidence to the contrary the disclosed prior art antibody binds an epitope from the

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peptide, SEQ.ID.NO: 17, 20, 26, 29, 30 or 31. Since the Office does not have the facilities for examining and comparing applicants' antibody and antibody of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed antibody and antibody of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

6. Claims 60 and 62 are rejected 35U.S.C.(103 a) as being unpatentable over Kohler et al 1990 (Infection and Immunity, 58, 1943-1950) in view of Harlow and Lane 1988 (Antibodies; Cold Spring Harbor) or Lerner (Adv.Immunol 1984, 136; 1-44).

Kohler et al 1990 et al teach the gene of *Listeria* that encodes a major extracellular protein. Further, the prior art teaches the complete nucleotide as well as deduced amino acid sequences (abstract, Fig 3) of this protein. Further the prior art teaches that internal r-iap fragment is specific for *L.monocytogene* and upstream of *dth18* gene are unique to this *L.monocytogene*. The prior art clearly suggests the restriction fragment length polymorphism detected with the *iap* gene and the *hlya* gene may be useful in identifying and distinguishing virulent *L.monocytogene* strains. Further, Kohler et al teaches that there are regions of the p60 molecule that are specific for pathogenic *Listeria* and teaches a process that can be used for the preparation of anti-p60 antibodies (see page 1944, second column, third paragraph. However, the prior art does not teach raising antibodies against peptides of p60. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to make monoclonal antibodies using the readily available p60 protein with a reasonable expectation of success because Kohler teach that *iap* gene and the *hlya* gene may be useful in identifying and distinguishing virulent *L.monocytogene* strains). An artisan of ordinary skills would have been motivated in applying the art disclosed by Kohler to either Lerner who teaches that peptides

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derived from the sequence of the whole protein (pages 1-44) could be used to raise antibodies or Harlow and Lane who teaches how to make monoclonal antibodies (Chapter 6) making a monoclonal antibodies because it would help in identifying and distinguishing virulent L.monocytogene strains. One of ordinary skill in the art would also know how to make monoclonal antibodies to p60 protein and identify the epitopes which bind to the antibodies. The claimed invention is prima facie obvious in view of Kohler et al 1990 (Infection and Immunity, 58, 1943-1950) and Lerner or Harlow and Lane 1988 (Antibodies; Cold Spring Harbor) absent any convincing evidence to the contrary.

#### **Status of Claims**

7. No claims are allowed

#### **Conclusion**

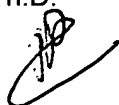
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

8/21/01



MARK NAVARRO  
PRIMARY EXAMINER